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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,499	12/19/2005	Toshihiro Shirouzu	KUZ00027US.NP	9337
7590 Licata & Tyrrell 66 East Main Street Marlton, NJ 08053			EXAMINER HUYNH, CARLIC K	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/561,499	SHIROUZU ET AL.	
	Examiner	Art Unit	
	Carlic K. Huynh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 3, 8 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>19 December 2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-13 are pending in the application in response to the restriction requirement submitted on August 27, 2007. Accordingly, claims 1-13 are being examined on the merits herein.

Election/Restrictions

2. Applicants' election with traverse of the election of species of: (1) terbinafine hydrochloride as the antitrichophyton; (2) 1-menthol as the menthol analogue; (4) isopropylmethylphenol as the bactericidal compound; (5) dibucaine hydrochloride as the local anesthetic; (6) chlorpheniramine maleate as the antihistamine; and (7) glycyrrhetic acid as the anti-inflammatory drug, in the reply filed on October 23, 2007 is acknowledged. The traversal is on the ground(s) that the special technical feature of the instant invention is not taught by Takuzo et al.

Applicants' arguments were not found persuasive. The special technical feature of the instant invention is an antitrichophyton mixed with at least one of 1-menthol, a menthol analogue, or a bactericidal compound (see instant claim 1). Moreover, there is a search burden for an antitrichophyton because each antitrichophyton is structurally distinct from one another. There is a search burden for a menthol analogue because each menthol analogue is structurally distinct from one another. There is a search burden for a bactericidal compound because each bactericidal compound is structurally distinct from one another. There is a search burden for a

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local anesthetic because each local anesthetic is structurally distinct from one another. There is a search burden for an antihistamine because each antihistamine is structurally distinct from one another. There is a search burden for an anti-inflammatory drug because each anti-inflammatory drug is structurally distinct from one another.

Claims 3, 8, and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made with traverse in the reply filed on October 23, 2007.

Accordingly, claims 1-2, 4-7, and 9-12 are being examined on the merits herein.

Thus the election of species requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on December 19, 2005, is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, 4-7, and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2002/0086039) in view of Kimura et al. (US 6,133,327), Kuhner et al. (US

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2003/0194445), Packman (US 4,945,084), Blackman (US 4,873,265), and Mekata (US 6,581,807).

Lee et al. teach topical formulations including foot care products for treating athlete's foot (page 2, paragraph [0023]; and page 19, paragraph [0220]). The foot care products including terbinafine hydrochloride (page 19, paragraph [0224]).

Lee et al. does not teach 1-menthol, isopropylmethylphenol, dibucaine hydrochloride, chlorpheniramine maleate, and glycyrrhetinic acid.

Kimura et al. teach an aerosol preparation for treating athlete's foot comprising 0.001 to 10% 1-menthol (abstract; and column 3, lines 17-21). It would be obvious that the aerosol preparation may be administered topically. For example the aerosol preparation for athlete's foot may be a spray to be applied to the affected foot.

Kuhner et al. teach an isopropylmethylphenol composition, to be administered topically, for the treatment of athlete's foot (page 4, paragraphs [0056] and [0066]; and page 6, paragraph [0083]).

Packman teaches a topical treatment for athlete's foot comprising dibucaine hydrochloride (abstract; column 5, lines 19-25; and column 6, lines 12-14).

Blackman teaches a topical antihistamine-containing composition for the treatment of athlete's foot (column 3, lines 55-65). The antihistamine may be chlorpheniramine maleate (column 7, line 4).

Mekata teaches an aerosol product for the treatment of athlete's foot comprising a composition of glycyrrhetinic acid (column 5, line 36; and column 7, lines 28-33). It would be

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obvious that the aerosol composition may be administered topically. For example the aerosol composition for athlete's foot may be a spray to be applied to the affected foot.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the pharmaceutical compositions of Lee et al. to contain 1-menthol, isopropylmethylphenol, dibucaine hydrochloride, chlorpheniramine maleate, and glycyrrhetinic acid because the compositions of Kimura et al. disclose 1-menthol and according to Kimura et al., 1-menthol is used to treat athlete's foot, because the compositions of Kuhner et al. disclose isopropylmethylphenol and according to Kuhner et al., isopropylmethylphenol is used to treat athlete's foot, because the compositions of Packman disclose dibucaine hydrochloride and according to Packman, dibucaine hydrochloride is used to treat athlete's foot, because the compositions of Blackman disclose chlorpheniramine maleate and according to Blackman, chlorpheniramine maleate is used to treat athlete's foot, and because the compositions of Mekata disclose glycyrrhetinic acid and according to Mekata, glycyrrhetinic acid is used to treat athlete's foot.

The motivation to combine the pharmaceutical compositions of Lee et al., to the compositions of Kimura et al., Kuhner et al., Packman, Blackman, and Mekata is that the compositions of Kimura et al., Kuhner et al., Packman, Blackman, and Mekata disclose 1-menthol, isopropylmethylphenol, dibucaine hydrochloride, chlorpheniramine maleate, and glycyrrhetinic acid, respectively, and that such compositions can be used to treat athlete's foot.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third

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composition that is to be used for the very same purpose”. *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding the amounts of the weight of 0.1-10% of the anti-trichophyton drug in the composition, as recited in claim 2, it is noted that Lee et al. teach terbinafine hydrochloride (page 19, paragraph [0224]). Since Lee et al. teach terbinafine hydrochloride, it would be obvious that the composition contains 0.1 to 10% by mass of terbinafine hydrochloride, which closely meets the amounts of weight of the anti-trichophyton drug set forth in claim 2. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the anti-trichophyton drug provided in a composition, according to the guidance set forth in Lee et al., to provide a composition having desired weight of the anti-trichophyton drug. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Regarding the amounts of the weight of 0.5-5% by mass of 1-menthol in the composition, as recited in claim 2, it is noted that Kimura et al. teach 0.001 to 10% 1-menthol (column 3, lines 17-21), which closely meets the amounts of weight of 1-menthol set forth in claim 2. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of 1-menthol provided in a composition, according to the guidance set forth in Kimura et al., to provide a composition having desired weight of 1-menthol. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

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Conclusion

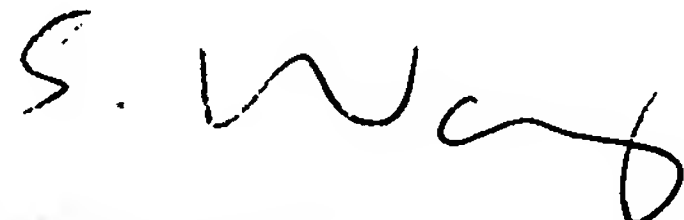
4. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh


SHENGJUN WANG
PRIMARY EXAMINEE